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Docket No. 255.00010122**IN THE UNITED STATES PATENT AND TRADEMARK OFFICE**

Applicant(s): Lisa K. NOLAN et al.) Group Art Unit: 1645
Serial No.: 09/738,599) Examiner: Sarvamangala J. N. Devi
Confirmation No.: 1240)
Filed: 15 December 2000)
For: NUCLEIC ACID ENCODING AN AVIAN E. COLI ISS POLYPEPTIDE &
METHODS OF USE

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Name: Rachel Gagliardi-Gebhardt

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JUN 12 2006

PATENT
Docket No. 255.00010122IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant(s):	Lisa K. NOLAN et al.)	Group Art Unit:	1645
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PRE-APPEAL BRIEF REQUEST FOR REVIEW

Mail Stop AF
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Sir:

Appellants hereby request a Panel Review of the seventh Office Action, dated January 13, 2006, in the above-identified application. This request is being filed with a Notice of Appeal.

Status of the Claims

The pending claims are claims 30-33, 37-42, 44-45, and 67-70 of which claims 30-33 and 69 are allowed and claims 37-42, 67-68, and 70 stand rejected, and claims 44-45 are objected to. Claims 35-36, 46-66, and 71-73 were canceled in the Amendment submitted June 8, 2006, to decrease the number of issues presented for review in this Pre-Appeal Brief Request for Review.

Review is requested for the following reasons:Rejection of claims 37-40 and 67

Claims 37-40 and 67 stand rejected under 35 U.S.C. § 102(b) as being anticipated by Barondess et al. (Nature, 344:871-874, 1990) as evidenced by Harlow et al. (Antibodies: A Laboratory Manual, Col Spring Harbor Laboratory, Chapter 5, p. 76, 1988) and Hunter (U.S.

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Filed: 11 March 2004

For: DECK ASSEMBLY FOR A SELF-PROPELLED, WALK-BEHIND ROTARY LAWN MOWER

Patent 5,554,372). This specific rejection has not been made before. However, the Barondess document has been used to reject these claims three separate times in the past. Barondess et al. was used to reject claims 37-40 under 35 U.S.C. § 102(b) in the first Office Action dated September 30, 2002 (and was later withdrawn in the Final Office Action dated April 18, 2003, in view of arguments presented and amendment of claim 37 to recite "a pharmaceutically acceptable carrier"). Barondess et al. was used in conjunction with Harlow et al. to reject claims 37-40 and 67 in the Final Office Action dated April 18, 2003 (and was later withdrawn in the third Office Action dated January 27, 2004, in view of an amendment of claim 37 to recite the subject matter of a dependent claim that was not rejected in view of Barondess et al. and Harlow et al.). Barondess et al. was used again in conjunction with Harlow et al. to reject claims 37-40 and 67 in the fourth Office Action dated July 30, 2004 (and was later withdrawn in the fifth Office Action dated January 27, 2005, in view of arguments presented).

The Examiner asserts that claims 37-40 and 67 are inherently anticipated by Barondess et al., and that Harlow et al. or Hunter are used to show that every element of the claimed subject matter is disclosed by Barondess et al. (Office Action at page 7, first full paragraph). It is respectfully submitted that this rejection of claims 37-40 and 67 under 35 U.S.C. § 102(b) lacks an essential element required to establish a *prima facie* rejection. Specifically, Barondess et al. does not disclose the claimed composition comprising a pharmaceutically acceptable carrier, and Harlow et al. and Hunter do not show that Barondess et al. inherently disclose the claimed composition.

Independent claim 37 recites, *inter alia*,

"An immunogenic composition comprising: an isolated nucleic acid molecule comprising a nucleotide sequence encoding a polypeptide comprising an avian *E. coli* lss polypeptide or an immunogenic fragment or immunogenic subunit of the avian *E. coli* lss polypeptide . . . and a pharmaceutically acceptable carrier."

Appellants have previously argued that Barondess et al. do not disclose the claimed composition comprising a pharmaceutically acceptable carrier (see responses submitted January 30, 2003 (page 21, first full paragraph) and November 1, 2004 (page 11, third full paragraph)).

Hunter is cited by the Examiner to show Barondess et al. inherently disclose a pharmaceutically acceptable carrier:

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"the prior art *E. coli* host cell expressing the Iss polypeptide fragment or subunit . . . inherently contains *E. coli* lipopolysaccharide, which lipopolysaccharide is known in the art to serve as an intrinsic adjuvant (i.e., pharmaceutically acceptable carrier). For example, Hunter taught that gram negative bacterial lipopolysaccharide serve as immunomodulating agents and immunological adjuvants (see first sentence under Example 17 of Hunter). Clearly, the prior art *E. coli* host cell expressing the Iss polypeptide or subunit . . . and comprising the endogenous lipopolysaccharide adjuvant serves as an immunogenic composition and anticipates the instantly claimed product."

Office Action at page 6, emphasis added.

The toxicity of lipopolysaccharide is well known, and the text of Hunter referenced by the Examiner acknowledges this:

"It has long been recognized that lipopolysaccharides from gram negative bacteria are effective immunomodulating agents and immunologic adjuvants. However, the toxicity of these materials has impeded their development as adjuvants."

Hunter, col. 28, lines 30-33, emphasis added (also see Hunter at col. 5, lines 13-17).

There is "a clear definition in the specification" (M.P.E.P §2111.01(I)) of pharmaceutically acceptable carrier as "a carrier(s) that is 'acceptable' in the sense of being compatible with the other ingredients of a composition and not deleterious to the recipient thereof." (specification at page 44, lines 14-16, emphasis added). Since lipopolysaccharide is toxic it would be deleterious to the recipient thereof, therefor it cannot be considered a pharmaceutically acceptable carrier. Thus, Hunter cannot be used to show that Barondess et al. inherently discloses the claimed composition comprising a pharmaceutically acceptable carrier.

Furthermore, "[i]n relying upon the theory of inherency, the examiner must provide a basis in fact and/or technical reasoning to reasonably support the determination that the allegedly inherent characteristic necessarily flows from the teachings of the applied prior art" (emphasis in original). M.P.E.P §2112. The Examiner has not made that showing. The doctrine of inherency is not available to supplement the demonstrated deficiencies of Barondess et al.

Accordingly, Appellants submit that Barondess et al. clearly fails to teach each and every element of independent claim 37 and, thus, fails to satisfy the objective criteria required to anticipate that claim. It is further submitted that claims 38-40, 44, 45, and 67 are novel in view of their dependence. Review and withdrawal of this rejection are respectfully requested.

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Rejection of claim 41

Claim 41 stands rejected under 35 U.S.C. §103(a) as unpatentable over Barondess et al. as applied to claim 37 above and further in view of Applicant's admitted state of the art.

This rejection is identical, word for word, with the rejection present at pages 7-8, paragraph 20, in the previous (sixth) Office Action (dated August 10, 2005). However, the present (seventh) Office Action states at page 3, paragraph 8, that this rejection is withdrawn.

Since the Examiner withdrew this rejection in view of arguments presented by the Appellants, and the Examiner has not presented any additional argument to support a prima facie case of obviousness, Appellants submit that the Examiner has not met the burden of establishing a prima facie case of obviousness. Review and withdrawal of this rejection are respectfully requested.

Rejection of claims 42 and 68

Claims 42 and 68 stand rejected under 35 U.S.C. §103(a) as unpatentable over Barondess et al. as applied to claim 38 above and further in view of Krieg et al.

With respect to claim 42, this rejection is identical, word for word, with the rejection present at pages 8-9, paragraph 21, in the previous (sixth) Office Action (dated August 10, 2005). However, the present (seventh) Office Action states at page 3, paragraph 9, that this rejection of claim 42 is withdrawn.

Since the Examiner withdrew this rejection in view of arguments presented by the Appellants, and the Examiner has not presented any additional argument to support a prima facie case of obviousness, Appellants submit that the Examiner has not met the burden of establishing a prima facie case of obviousness. Review and withdrawal of this rejection of claim 42 are respectfully requested.

With respect to claim 68, please refer to the earlier submitted argument in the response submitted November 10, 2005, specifically page 14, last paragraph, through page 15. Although this earlier submitted argument relates to claim 42, both claims 42 and 68 recite "an immunostimulatory sequence," and the present rejection of claim 68 is based on this recitation.

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Since the Examiner has not established a prima facie case of obviousness, review and withdrawal of this rejection of claim 68 are requested.

Claim 70

Claim 70 is considered to be rejected by the Examiner (see paragraph 17 of the present Office Action); however, claim 70 is not included in any formal rejection. Since no rejection of claim 70 is set forth, claim 70 is allowable.

Summary

For at least the foregoing reasons, Appellants respectfully request that the Panel review and reverse the rejections of claims 37-42, 44-45, 67-68, and 70 in the above-identified application.

Seven Office Actions have been issued by the Office in this application, and the pending claims have had a limited number of amendments during prosecution. It is respectfully submitted that the Examiner has had ample opportunity to conduct a complete examination of this application. A Panel Decision allowing the application on the existing claims be issued is respectfully requested.

CERTIFICATE UNDER 37 C.F.R. 1.8:

The undersigned hereby certifies that this paper is being transmitted by facsimile in accordance with 37 CFR §1.6(d) to the Patent and Trademark Office, addressed to Mail Stop AF, Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450, on this 12th day of June, 2006, at 3:43 pm, (Central Time).

Signature: Raasch & GebhardtName: Raasch & GebhardtDate: June 12, 2006

Respectfully submitted by

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